510K(k) SUMMARY K112840

SUBMITTER:	Seebreath AB Kontoret Nybroviken Birger Jarlsgatan 2, 5tr SE-114 34 Stockholm Sweden Phone: +46(0)8 50565100
DATE PREPARED:	**September 25th 2011**
DEVICE NAME:	**CapnoDura Combi & CapnoDura Pedi CO_2 Detectors**
CLASSIFICATION NAMES:	**Carbon Dioxide Gas Analyzer**

JUL 13 2012

Device Description:

The CapnoDura Combi & CapnoDura Pedi CO_2 Detectors are non-sterile, single use, colorimetric CO_2 detectors to be connected between a breathing circuit and a tracheal tube. The colorimetric indicator area in the center of the device indicates the presence of carbon dioxide during the breathing to assist verification of tracheal tube placement in trachea following intubation and to observe respiration by the detector's color changes The indicator panel is blue when no CO_2 is present, green at intermediate concentrations and yellow when approximately 5% CO_2 is present. A permanent blue or blue-green color indicates absence of exhaled CO_2. A damaged indicator will exhibit a permanent yellow or white color.

The unit has a printed reference scale against which the actual indicator color may be compared to obtain an approximate CO_2 concentration. There are two sizes of the detector, Combi and Pedi, and these will fit with the breathing circuit and tracheal tube connections for both adults and children, respectively. The connections are ISO standard dimensions

Device	510(k) Document Number	Date Cleared	Indications
Mercury Medical Mini Stat CO2 Detector Model 10-55371	K031411	7/30/2003	Carbon Dioxide Gas Analyzer
Mercury Medical Stat CO2 Detector Model 10-55370	K021576	11/4/2002	Carbon Dioxide

Indications for Use:

To assist verification of tracheal tube placement in the trachea following intubation and to observe respiration by the detector's color changes.

CapnoDura Pedi: To provide a semi quantitative visualization of the CO2 in the patient airway. This device is to be used on patient weighting 1 kg – 15 kg.

CapnoDura Combi: To provide a semi quantitative visualization of the CO2 in the patient airway. This device is to be used on patient weighting 10 kg or above.

Both the CapnoDura Pedi and the CapnoDura Combi are adjuncts in patient assessment to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician.

Technological Characteristics:

Technologically, both the new device and the predicate device are substantially equivalent, partially identical. The form, fit, function and method of operation are similar Any differences between the two devices do not raise new questions of safety and effectiveness

Performance Data and pre clinical testing:

Results of verification testing indicates that the product meets the established performance requirements. In vitro performance tests were performed for dead space volume, flow resistance, color change, conical fitting measurements/ tolerances, fitting tightness and packaging integrity.
The material used are the same as in predicate products and no new biocompatibility testing was needed.

Conclusions:

Based on the 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the proposed device is substantially equivalent to the existing legally marketed device under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Anette Sjögren
QA/RA Manager
Seebreath AB
Morkullevägen 31
Bjärred
SWEDEN 23736

JUL 13 2012

Re: K112840
Trade/Device Name: CapnoDura Combi & CapnoDura Pedi CO_2 Detectors
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: June 23, 2012
Received: July 2, 2012

Dear Ms. Sjögren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION XIII.

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: CapnoDura Combi & CapnoDura Pedi CO_2 Detectors

Indications for Use:

CapnoDura Pedi: To provide a semi quantitative visualization of the CO2 in the patient airway. This device is to be used on patient weighing 1 kg – 15 kg. It is an adjunct in patient assessment to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician. To assist verification of tracheal tube placement in the trachea following intubation and to observe respiration by the detector's color changes.

CapnoDura Combi: To provide a semi quantitative visualization of the CO2 in the patient airway. This device is to be used on patient weighing 10 kg or above. It is an adjunct in patient assessment to be used in conjunction with other methods to determine clinical signs and symptoms by or on the order of a physician. To assist verification of tracheal tube placement in the trachea following intubation and to observe respiration by the detector's color changes.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz Page __ of __

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112880